REMARKS

This amendment is responsive to the Office Action dated February 25, 2004. Applicants have amended claims 1, 7-10, 18, 20, 29 and 53 and have canceled claim 6. Claims 1-5 and 7-59 are pending.

Applicants have made some amendments as a matter of form, which are administrative and are not intended to narrow the scope of the claims. Applicants have added the word "and" to claim 53, and have changed the word "proximal" to the more conventional "proximate."

Claim 1 has been amended to include elements of claim 6, and claims 7-10 have been amended to be dependent upon claim 1 instead of claim 6.

Claim Rejections Under 35 U.S.C. § 102

Rejections in view of Kroll

In the Office Action, the Examiner rejected claims 1-4, 6, 8, 9 and 11-14 under 35 U.S.C. § 102(b) as being anticipated by Kroll (U.S. Pat. No. 5,772,690). Applicants respectfully traverse the rejections, particularly to the extent the rejection may be considered applicable to amended claims. For a claimed invention to be anticipated by a cited reference, the cited reference must disclose each and every element of the claimed invention. E.g., Trintec Indus. Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1579, 1599 (Fed. Cir. 2002); Lewmar Marine, Inc. v. Barient, Inc., 3 USPQ2d 1766, 1767 (Fed. Cir. 1987). Kroll fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Claim 1, as amended, is independent, and claims 2-4, 8, 9 and 11-14 depend directly or indirectly on claim 1. Thus claims 1-4, 8, 9 and 11-14 include the elements of independent claim 1.

Independent claim 1, as amended, recites a device comprising a medical device and a pouch comprising an anchor that fastens the pouch to the medical device, the pouch containing an electrode. According to the Examiner, Kroll discloses a pouch (denoted by reference numeral 62 in Kroll Fig. 6 and by reference numeral 162 in Kroll Fig. 7) that contains surrogate electrode 64. The Examiner is incorrect. As is plainly shown in Kroll Fig. 7, surrogate electrode 64 is

separated from pouch 162 by a considerable distance, and is not contained in pouch 162, as recited in independent claim 1.

The Kroll surrogate electrode is not only not inside the Kroll pouch, the Kroll apparatus is specifically configured so that the surrogate electrode could not be inside the Kroll pouch, for the simple reason that the pouch is an implanted element and the surrogate electrode is an external element attached to the skin of the patient. Kroll col. 4, lines 43-45; col. 5, lines 8-11; col. 6, lines 3-4, 21-23. Kroll therefore does not suggest that the surrogate electrode could be inside the pouch.

In addition, Kroll fails to disclose or suggest an anchor that fastens the pouch to the medical device, as recited in claim 1, as amended (formerly recited in claim 6, now canceled). The Examiner refers Applicants to the tab shown in Kroll Fig. 6, but the tab is for connecting the surrogate electrode to the pouch, not for anchoring the medical device to the pouch. Col. 6, lines 23-24. Although the Kroll ICD (implantable cardioverter-defibrillator) may be in contact with the Kroll pouch, Kroll does not describe any anchor that fastens them together, as recited in claim 1, as amended. Nor does Kroll describe any mating member on the ICD that receives the anchor, as recited in claim 9.

Kroll does not disclose or suggest right and left electrodes, as recited in claim 13. Kroll Figs. 3, 4 and 7 depict the surrogate electrode either across the top of the chest of the patient, or on the patient's left side. Kroll does not describe or suggest use of left and right surrogate electrodes.

Kroll also does not disclose or suggest a lip on the medical device that engages the pouch, as recited by claim 14.

For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicants' claims 1-4, 6, 8, 9 and 11-14 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Rejections in view of Walters et al.

In the Office Action, the Examiner rejected claims 1, 5, 17, 18, 28-31,34, 53, 55 and 56 under 35 U.S.C. § 102(b) as being anticipated by Walters et al. (U.S. Pat. No. 6,048,640). Applicants respectfully traverse the rejection. Walters et al. fail to disclose each and every

feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provide no teaching that would have suggested the desirability of modification to include such features.

Claims 1 and 5

The Examiner is obligated to set forth a full and reasoned explanation for the Examiner's decision, and must set forth findings and the grounds thereof, as supported by the record. In re Lee, 61 USPQ2d 1430, 1432-33 (Fed. Cir. 2002). In connection with claims 1 and 5, the Examiner has not complied with this obligation imposed by law. As will be mentioned below, the Examiner failed to comply with this obligation in regard to other claims as well, rejecting the claims without setting forth any reasoned basis for doing so.

In particular, claims 1, as amended, and 5 recite a device comprising a medical device and a pouch comprising an anchor that fastens the pouch to the medical device, the pouch containing an electrode. The Examiner did not point out where Walters et al. discloses a pouch that is fastened to a medical device. Furthermore, Applicants believe that Walters et al. do not disclose or suggest a pouch or package fastened to a medical device. In addition, Walters et al. do not disclose or suggest an anchor, as recited by claims 1 (previously recited in claim 6), as amended, and 5. For at least these reasons, Walters et al. would not support a prima facie case for anticipation of Applicants' claims 1 and 5 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claims 17-18, 28-31, 34, 53, 55-56

Claims 17 and 18 recite a device comprising a pouch containing a defibrillation electrode, the pouch comprising a handle that when pulled causes the pouch to open. Claims 28-31 and 34 recite a method comprising sealing a defibrillation electrode in a pouch and constructing a handle on the pouch that when pulled causes the pouch to open. Claims 53 and 55-56 recite a method comprising obtaining a pouch containing a defibrillation electrode and opening the pouch by pulling a handle.

According to the Examiner, the end 14 of the Walters pouch discloses a handle. Walters et al. do not disclose or suggest a handle in any way.

Fig. 1 of Walters et al. shows no handle of any kind on end 14. Nowhere do Walters et al. mention or suggest a handle of any kind.

The Walters pouch is not opened by pulling on any handle. On the contrary, Walters et al. describe tearing open the pouch without the use of any handle: "When a need for the electrode arises, the operator merely tears off the first end 14, and removes the electrodes 28, 30 from the package as shown in FIG. 1." Walters et al. col. 4, lines 20-23.

Walters et al. do not disclose or suggest any handle and therefore Walters et al. do not anticipate claims 17-18, 28-31, 34, 53 or 55-56.

In addition, claim 18, as amended, recites a device comprising a notch proximate to the handle, the pouch tearing at the notch when the handle is pulled. Similarly, claims 29-30 recite a method that comprises forming a notch in the pouch proximal to the handle, the pouch tearing at the notch when the handle is pulled. Not only do Walters et al. not disclose or suggest a handle, Walters et al. do not disclose or suggest any notch. Fig. 1 of Walters et al. shows no notch, and Walters et al. never mention a notch. The Examiner asserted that a notch was present, but did not set forth findings and the grounds for this assertion, supported by the record.

Furthermore, claim 31 recites a method wherein constructing a handle on the pouch comprises attaching the handle to the pouch. Nowhere do Walters et al. mention or suggest attaching any kind of handle to the pouch, and the Examiner did not include a reasoned analysis showing where Walters et al. disclose this element.

Moreover, claim 55 recites a method that includes removing a liner from the defibrillation electrode. Walters et al. do not disclose or suggest any liner. Walters Fig. 1 shows no liner, and the description omits any mention of any removable liner. Col. 3, lines 35-40. Once again, the Examiner failed to provide any findings or grounds that would support rejection of claim 55.

For at least these additional reasons, Walters et al. do not anticipate claims 18, 29-30, 31 or 55.

Rejections in view of Faller et al.

In the Office Action, the Examiner rejected claims 1-4, 6, 10, 17-20, 28-31, 53, 55 and 56 under 35 U.S.C. § 102(e) as being anticipated by Faller et al. (U.S. Pat. No. 6,611,709). Applicants respectfully traverse the rejection. Faller et al. fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provide no teaching that would have suggested the desirability of modification to include such features.

In addition, the Examiner did not set forth a full and reasoned explanation for the Examiner's decision, and did not set forth findings and the grounds thereof, as supported by the record, as required by In re Lee, 61 USPQ2d at 1432-33. The Examiner's basis for rejecting claims 1-4, 6, 10, 17-20, 28-31, 53, 55 and 56 under 35 U.S.C. § 102(e) as being anticipated by Faller et al., in its entirety, is: "Faller et al. disclose a notch comprising tear line 32."

Claims 1-4, 6, 10

Applicants have amended claim 1 to recite elements of claim 6, and have canceled claim 6. As a result, claims 1-4 and 10 recite a medical device and a pouch comprising an anchor that fastens the pouch to the medical device. Faller et al. fail to disclose and a pouch comprising an anchor that fastens the pouch to the medical device, and provide no teaching that would have suggested the desirability of modification to include such features.

With respect to claim 1 (which has been amended to include the elements of claim 6), the Examiner did not identify which element of Faller et al. the Examiner deemed to correspond to an anchor. The only element in Faller et al. that could remotely be viewed as an anchor is expiration-indicating tab 12, and yet tab 12 is clearly not an anchor of any kind. On the contrary, tab 12 is designed to tear away upon opening of cover 16 of the Faller device. E.g., Faller et al. col. 2, lines 1-4; col. 3, lines 39-40, 52-55; col. 4, lines 48-49. Rather than fastening the pouch (what Faller et al. call electrode package 10) to the medical device, as recited in claim 1, the Faller tab is intended to tear along tear line 32 when cover 16 is opened. As Fig. 3 of Faller et al. clearly shows, the adhesive part of tab 12 does not anchor electrode package 10 at all, but as soon as cover 16 is opened, the adhesive part fractures or tears away and is disconnected from electrode package 10.

Indeed, the purpose of the Faller tab is not to serve as an anchor. Rather, tab 12 serves as an indicator of whether cover 16 has been opened and whether any tampering has occurred. Tab 12 also permits a user to ascertain whether the electrodes have expired. E.g., col. 2, lines 39-53, 60-61; col. 3, lines 10-12. As part of the anti-tampering function of tab 12, tab 12 is designed not to fasten the electrode package but rather to fracture, tear or otherwise disengage from the electrode package, and thereby to show possible tampering.

Furthermore, the Faller tab is not a part of the pouch, as recited in claims 1-4 and 10, but is a distinct element that need not be attached to the pouch in any way. Faller et al. notes that "the tab could be a separable member removed from the electrode package and connected to the base and cover," in other words, the tab need not associated with the electrode pouch at all in order to function. Col. 4, lines 28-30.

Claim 10, as amended, recites the pouch comprising a notch and a handle that, when pulled, causes the handle to move away from the anchor and causes the pouch to tear at the notch. Faller et al. disclose none of these elements.

Nothing in Faller et al. shows any element of electrode package 10 that is a handle, and nothing in Faller et al. shows any element of electrode package 10 that is a notch, as recited in claim 10. The Examiner equates tear line 32 with a notch, but clearly tear line 32 is not a notch. According to Faller et al., tear line 32 is the site where there is a disparity of tear strength, due to the fact that end region 26 of tab 12 consists "only of paper." Col. 3, lines 20-44. When a user opens cover 16, tab 12 fractures at tear line 32 not because of the presence of any notch, but because that is the fracturable part tab 12.

For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicants' claims 1, as amended, and 2-4 and 10 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claims 17-20, 28-31, 53, 55-56

Claims 17-20 recite a device comprising a pouch containing a defibrillation electrode, the pouch comprising a handle that when pulled causes the pouch to open. Claims 28-31 recite a method comprising sealing a defibrillation electrode in a pouch and constructing a handle on the pouch that when pulled causes the pouch to open. Claims 53 and 55-56 recite a method comprising obtaining a pouch containing a defibrillation electrode and opening the pouch by pulling a handle. Faller et al. fail to disclose and a pouch comprising handle that when pulled causes the pouch to open, and provide no teaching that would have suggested the desirability of modification to include such features.

Faller et al. include no disclosure or suggestion that a handle be used to open the pouch. For that matter, Faller et al. do not describe any mechanism for opening the pouch. The Examiner did not include a reasoned decision showing where Faller et al. disclose a handle.

Tab 12 of Faller et al. is certainly not a handle. Although opening cover 16 causes tab 12 to tear, the tearing of tab 12 does not open electrode package 10. As is shown clearly in Fig. 3 of Faller et al., the torn tab in no way opens electrode package 10. Tab 122 can therefore not be a handle as recited in claims 17-20, 28-31, 53 and 55-56.

Claims 18, as amended, and 19-20 recite a notch proximate to the handle. Claims 29-30 recite forming a notch in the pouch proximate to the handle. As noted above, Faller et al. does not disclose or suggest a notch. In addition, if the Examiner equates tear line 32 with a notch, then tab 12 cannot be a handle as recited in claims 18-20 and 29-30. As recited in claims 18-20 and 29-30, the notch is "proximate to" the handle, not a part of the handle.

Claim 19 recites wherein the handle is on one side of the notch, the pouch further comprising an anchor on another side of the notch. Claim 30 includes a similar recitation. As pointed out above, Faller et al. do not disclose or suggest an anchor. Furthermore, Faller et al. do not disclose or suggest a handle on one side of the notch and an anchor on the other side, as recited by claims 19 and 30.

Claim 20 recites a tear strip proximate to the notch, wherein causing the pouch to open comprises causing the pouch to tear along the tear strip. Faller et al. do not disclose or suggest this element, either, and the Examiner did not identify any such element in Faller et al. Tearing at tear line 32 does not open Faller electrode package 10.

Claim 55 recites removing a liner from the defibrillation electrode. Faller et al. do not disclose or suggest this element, and the Examiner did not identify any such element in Faller et al.

For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicants' claims 17-20, 28-31, 53 and 55-56 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Rejections in view of Kawaguchi

In the Office Action, the Examiner rejected claims 1, 6 and 7 under 35 U.S.C. § 102(b) as being anticipated by Kawaguchi . (U.S. Pat. No. 3,685,645). Applicants respectfully traverse the rejection to the extent such rejection may be considered applicable to the amended claims. Kawaguchi fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Claim 1, as amended to include elements of claim 6, recites a device comprising a medical device and a pouch comprising an anchor that fastens the pouch to the medical device, the pouch containing an electrode. Claim 7, as amended, depends on claim 1 and recites "wherein the anchor is substantially cylindrical."

Kawaguchi does not disclose any element that fastens the Kawaguchi package to any medical device. Foldable interconnecting portion 32, which the Examiner equates with an anchor, does not fasten package 10 to any medical device in any way. On the contrary, foldable interconnecting portion 32 is a portion of package 10 between pockets 12 and 14, which hold electrodes 16 and 18. Interconnecting portion 32 is bounded by scored tear lines 34 and 36, and by tearing away interconnecting portion 32, a user can obtain access to each defibrillation electrode. Kawaguchi col. 2, lines 1-4, 32-45. Interconnecting portion 32 is not an anchor that fastens the package to a medical device in any way.

Moreover, interconnecting portion 32 is not substantially cylindrical, as recited in claim 7. Fig. 1 of Kawaguchi plainly shows interconnecting portion 32 as planar. Figs. 2 and 3 of Kawaguchi plainly show interconnecting portion 32 as a folded plane, or U-shape, not as a substantially cylindrical anchor. Furthermore, it is obvious that once interconnecting portion 32 is torn away, it cannot possibly be an anchor, as recited in claims 1 and 7.

For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicants' claims 1 and 7 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Rejection in view of Nova et al. ('885)

In the Office Action, the Examiner rejected claim 35 under 35 U.S.C. § 102(e) as being anticipated by Nova et al. (U.S. Pat. Appl. No. 2003/0114885). Applicants respectfully traverse the rejection. Nova et al. fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provide no teaching that would have suggested the desirability of modification to include such features.

Applicants note at the outset that the Examiner's rejection of claim 35 includes no reasoning in support of the rejection.

The rejection is without merit in any event. Claim 35 recites a device comprising a defibrillation electrode, a human figure printed on the defibrillation electrode and an electrode symbol printed on the human figure. Claim 35 further recites "wherein the human figure is oriented on the defibrillation electrode at an angle so that when the defibrillation electrode is applied to a patient with the head of the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented at the angle." Nova et al. do not disclose this element. The Examiner appears to have overlooked the "wherein" clause of claim 35.

Figs. 3 and 8 of Nova et al. show defibrillation electrodes, what Nova et al. refer to as "transducers." These transducers include human figures and an electrode symbol printed on the human figures, but in neither Fig. 3 nor Fig. 8 is either human figure "oriented on the defibrillation electrode at an angle so that when the defibrillation electrode is applied to a patient with the head of the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented at the angle," as recited in claim 35. Rather, the human figures are both oriented in the same way on the transducers.

The rearmost transducer shows a human figure with an electrode symbol oriented at an angle, but if that transducer were to be applied to a patient with the head of the patient and the head of the human figure in the same direction, the transducer would not be oriented at the angle shown in the figure, as recited in claim 35.

Claim Rejections Under 35 U.S.C. § 103

Rejections in view of Walters et al. and Bishay et al.

In the Office Action, the Examiner rejected claims 1, 16, 17, 26, 27, 28, 33, 35-38, 40-43, 45-53 and 56-59 under 35 U.S.C. § 103(a) as being unpatentable over Walters et al. in view of Bishay et al. (U.S. Pat. No. 5,951,598). Applicant respectfully traverses the rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

According to the Examiner, Walters et al. show all of the features of the claimed invention except for instructive pictures. The Examiner determined that Bishay et al. disclosed images on electrodes. The Examiner concluded that it would have been obvious to one of ordinary skill in the art to combine the images of Bishay et al. with the electrodes of Walters et al. because both references pertain to the same type of electrodes and because time is critical for fast electrode placement and a visual display on the electrode minimizes the time needed for an operator to place the electrodes on a patient.

Claims 1, 16, 17, 26, 28, 33

The Examiner previously rejected independent claim 1 under 35 U.S.C. § 102(b), citing of Walters et al. For the reasons given above, Walters et al. do not disclose or suggest the elements of claim 1, as amended. In addition, claim 1, as amended, includes no recitation pertaining to images on electrodes, and Bishay et al. do not disclose other elements of claim 1. Accordingly, citation of Bishay et al. is not relevant to claim 1.

Claim 16, which depends on claim 1, as amended, recites that the pouch comprises an instructive picture that illustrates placement of the electrode on a patient. Because Walters et al. do not disclose or suggest the elements of claim 1, as amended, Walters et al. do not disclose or suggest the elements of claim 16. The rejections of claims 1 and 16 under 35 U.S.C. § 103(a) should therefore be withdrawn.

Similarly, the Examiner previously rejected independent claim 17 under 35 U.S.C. § 102(b), citing of Walters et al. For the reasons given above, Walters et al. do not disclose or

suggest the elements of claim 17. Like claim 1, as amended, claim 17 includes no recitation pertaining to images on electrodes, and Bishay et al. do not disclose or suggest any of the elements of claim 17. Citation of Bishay et al. is not relevant to claim 17.

Claims 26 and 27, which depend on claim 17, recite that the pouch comprises an instructive picture that illustrates placement of one or more defibrillation electrodes on a patient. Walters et al. do not disclose or suggest the elements of claim 17, and therefore Walters et al. do not disclose or suggest the elements of claims 26 and 27, either. The rejections of claims 17, 26 and 27 under 35 U.S.C. § 103(a) should therefore be withdrawn.

The Examiner previously rejected independent claim 28 under 35 U.S.C. § 102(b), citing of Walters et al. Once again, claim 28 recites nothing pertaining to images on electrodes, and Bishay et al. neither disclose nor suggest any of the elements of claim 28. Citation of Bishay et al. is therefore irrelevant to claim 28. Furthermore, Walters et al. do not disclose or suggest the elements of claim 28 for the reasons given above.

Claim 33, which depends upon claim 28, recites a method that includes printing an instructive picture on the pouch illustrating placement of the electrode on a human figure. Once again, Walters et al. do not disclose or suggest the elements of claim 28, and therefore Walters et al. and Bishay et al. do not disclose or suggest the elements of claims 33. The rejections of claims 28 and 33 under 35 U.S.C. § 103(a) should therefore be withdrawn.

Claims 35-38, 40-43, 45-46

Independent claim 35 recites a device comprising a defibrillation electrode, a human figure printed on the defibrillation electrode and an electrode symbol printed on the human figure. Claim 35 further recites "wherein the human figure is oriented on the defibrillation electrode at an angle so that when the defibrillation electrode is applied to a patient with the head of the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented at the angle." Independent claim 41 recites a method comprising printing a human figure on a defibrillation electrode and printing an electrode symbol on the human figure on the defibrillation electrode. Claim 41 also recites "wherein the human figure is oriented on the defibrillation electrode at an angle so that when the defibrillation electrode is applied to a

patient with the head of the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented at the angle."

Once again, the Examiner appears to have overlooked the "wherein" clauses of claims 35 and 41. Walters et al. disclose nothing pertaining to images on defibrillation electrodes. Bishay et al., by contrast, mention images of human figures on electrodes. Bishay et al. do not disclose or suggest, however, a human figure oriented on the defibrillation electrode at an angle so that when the defibrillation electrode is applied to a patient with the head of the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented at the angle, as recited in claims 35 and 41.

Fig. 1 of Bishay et al. shows defibrillation electrodes with images. The images include human figures and an electrode symbols printed on the human figures, but Fig. 1 does not show either human figure "oriented on the defibrillation electrode at an angle so that when the defibrillation electrode is applied to a patient with the head of the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented at the angle," as recited in claims 35 and 41. Rather, the human figures are both oriented in the same way.

In addition, the orientation of the electrodes on the Bishay figures can be easily determined from the lead lines 16, 16' and their images, 30, 30'. Clearly, if the Bishay electrodes were to be applied to a patient with the head of the patient and the head of the human figure in the same direction, neither electrode would be oriented at the angle shown in the electrodes' figures, as recited in claims 35 and 41. Put another way, if the Bishay electrodes were to be applied to a patient and were oriented as shown in Fig. 1 of Bishay et al., the head of the patient and the head of the human figure would not be in the same direction.

Claims 36-38 and 40 depend on claim 35. Claims 42-43 and 45-46 depend on claim 41. Walters et al. and Bishay et al. fail to disclose or suggest the elements of claims 35 and 41, and therefore Walters et al. and Bishay et al. fail to disclose or suggest the elements of claims 36-38, 40, 42-43 and 45-46 as well.

In addition, Bishay et al. clearly fail to describe or suggest the elements of claims 36 and 42. Claims 36 and 42 recite "wherein the human figure is oriented on the defibrillation electrode at an angle so that when the defibrillation electrode is applied to a left side of the chest of the patient with the head of the patient and the head of the human figure in the same direction, the

defibrillation electrode will be oriented at the angle." If we assume for the sake of argument that the patient's head is in the twelve o'clock direction, then placement of Bishay electrode 12 on the left side of the chest of the patient as shown in Fig. 1 would cause lead line 16 to be at approximately the nine o'clock direction. The head of the Bishay figurine would therefore be in the three o'clock direction, which is a different direction from the patient's head.

Also, claim 38 recites the device comprising left and right defibrillation electrodes, with a liner affixed to the defibrillation electrodes, "wherein the color of the liner is distinct from the colors of the left and right defibrillation electrodes." Claim 45 likewise recites a liner with a color distinct from the electrodes. Walters et al. and Bishay et al. fail to disclose or suggest the elements of claim 38. Walters et al. mention nothing about a liner. In support of the rejection, the Examiner relies upon this passage from Bishay et al.: "Additionally, portions of the image may appear in an alternate color, such as red, or may be bolded, to enhance the operator's ability to quickly asses the correct location for the electrode pad. It is contemplated that a combination of color usage and bolding may be employed to enhance the readability of the images." Bishay et al. col. 5, lines 48-54.

This language from Bishay et al. does not talk about the color of the liner being distinct from the colors of the left and right defibrillation electrodes, as recited in claims 38 and 45. This language says nothing about distinct colors of liner and electrodes, but rather pertains to the readability of the images on the electrodes and the operator's ability to place the electrodes correctly on the patient.

For at least these reasons, the rejections of claims 35-38, 40-43 and 45-46 under 35 U.S.C. § 103(a) should therefore be withdrawn.

Claims 47-52

Independent claim 47 recites a device comprising a right defibrillation electrode including a first instructive picture and a left defibrillation electrode including a second instructive picture. Claim 47 also recites "wherein the first instructive picture includes a right electrode symbol on a first human figure, the first human figure oriented in a first direction" and "wherein the second instructive picture includes a left electrode symbol on a second human figure, the second human figure oriented in a second direction."

Walters et al. and Bishay et al. fail to disclose or suggest the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Walters et al. include no instructive pictures. The human figures disclosed by Bishay et al. show both human figures oriented in exactly the same direction. One Bishay human figure is not oriented in a first direction, with the other Bishay human figure oriented in a second direction, as recited in claim 47.

Claims 48-52 depend on claim 47. Walters et al. and Bishay et al. fail to disclose or suggest the elements of claim 47 and therefore Walters et al. and Bishay et al. fail to disclose or suggest the elements of claims 48-52 as well.

As noted above, neither Bishay et al. nor Walters et al. describe a liner with a color distinct from the colors of left and right defibrillation electrodes, as recited in claim 49.

Claim 50 recites a device in which "at least a portion of the right electrode includes a first color, at least a portion of the left electrode includes a second color, the right electrode symbol includes the first color and not the second color and the left electrode symbol includes the second color and not the first color." The discussion pertaining to color in Bishay et al., quoted above, does not disclose or suggest first and second colors, with the first color being exclusive to the right electrode symbol and the second color being exclusive to the left electrode symbol, as recited in claim 50.

Claim 51 recites "wherein the left electrode symbol is oriented in the first direction." The "first direction," as recited in claim 47, is the direction of orientation of the first human figure on the right electrode symbol. Neither Walters et al. nor Bishay et al. describe or suggest such an element. In Bishay et al., left electrode symbol 34 is not oriented in the same direction as the human figure 22' on right electrode 12'.

Claim 52 recites "wherein the second human figure is oriented on the defibrillation electrode at an angle so that when the left defibrillation electrode is applied to a patient with the head of the patient and the head of the second human figure in the same direction, the left defibrillation electrode will be oriented at the angle." As discussed above, neither Walters et al. nor Bishay et al. disclose or suggest this element.

For at least these reasons, the rejections of claims 47-52 under 35 U.S.C. § 103(a) should therefore be withdrawn.

Claims 53, 56-59

The Examiner previously rejected independent claim 53 under 35 U.S.C. § 102(b), citing of Walters et al. For the reasons given above, Walters et al. do not disclose or suggest the elements of claim 53. In addition, claim 53 includes no recitation pertaining to images on electrodes, and Bishay et al. includes no disclosure or suggestion of any of the elements of claim 53. Citation of Bishay et al. is irrelevant to claim 53.

Claims 56-59 depend on claim 53. Because Walters et al. do not disclose or suggest the elements of claim 53, Walters et al. do not disclose or suggest the elements of claims 56-59. The rejections of claims 53 and 56-59 under 35 U.S.C. § 103(a) should therefore be withdrawn.

Claim 59 recites the method of claim 53, and further recites "placing the defibrillation electrode on the chest of the patient and orienting the head of a human figure on the defibrillation electrode in the same direction as the head of the patient." Walters et al. and Bishay et al. do not disclose or suggest this element. As discussed above, placing Bishay defibrillation electrodes on the chest of the patient and orienting the head of the human figures on the defibrillation electrodes in the same direction as the head of the patient will result in the electrodes being oriented improperly. If the patient's head is assumed to be in the twelve o'clock direction, then Bishay electrode 12' is properly placed with the head of the human figure in the eleven o'clock direction, with lead line 30' in the five o'clock direction, and Bishay electrode 12 is properly placed with the head of the human figure in the three o'clock direction, with lead line 30 in the nine o'clock direction. Bishay et al. do not suggest placing the defibrillation electrode on the chest of the patient and orienting the head of a human figure on the defibrillation electrode in the same direction as the head of the patient, as recited in claim 59, and show the contrary.

For at least these reasons, the rejections of claims 53 and 56-59 under 35 U.S.C. § 103(a) should therefore be withdrawn.

Rejections in view of Walters et al., Bishay et al and Nova et al. ('070)

In the Office Action, the Examiner rejected claims 1, 15, 17, 23, 24, 25, 28, 32, 35, 39, 41, 43, 44, 53 and 54 under 35 U.S.C. § 103(a) as being unpatentable over Walters et al. in view of Bishay et al. and further in view of Nova et al. (U.S. Pat. No. 6,334,070). Applicants respectfully traverse the rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

According to the examiner, Nova et al. ('070) provide additional visual instruction that may be displayed for electrode package opening.

Applicants incorporate the above arguments as they pertain to claims 1, 17, 28, 35, 41, 43 and 53. Applicants further point out that claims 1, 17 and 28 do not recite elements pertaining to instructions. Citation of Nova et al. is irrelevant to these claims.

Applicants further point out that the Examiner failed to provide a reasoned decision by failing to point out which portions of Nova et al. were deemed to show the claimed elements. Presumably the Examiner refers to Nova et al. col. 11, lines 11-14, which state: "Although not shown, if the electrodes 16 are sealed within an electrode package, an additional visual instruction may be displayed for the electrode package opening action." This is the only passage in Nova et al. that pertains to instructions of any kind for opening any electrode package. No figures in Nova et al. disclose any electrode package or any figures thereon.

Claim 15 recites the device of claim 1, the pouch comprising an instructive picture that illustrates opening the pouch. Claim 23, which depends on claim 17 and claim 32, which depends on claim 28, recite similar elements. Walters et al. and Bishay et al. clearly do not disclose such an element, and neither Walters et al. nor Bishay et al. disclose or suggest any instructive picture of any kind on the pouch.

Nova et al. do not disclose or suggest this element, either. On the contrary, Nova et al. specifically describe "an instruction ... displayed for the electrode package opening action" that is displayed on a display 14, not on the package itself, as recited in claim 15. In particular, Nova et al. says: "The logic of the electrode attachment sequence begins in a block 240 and proceeds to a block 242 where the microprocessor 24 generates the visual instruction for electrode

attachment shown in FIG. 10H on the display 14 of the AED 10. Although not shown, if the electrodes 16 are sealed within an electrode package, an additional visual instruction may be displayed for the electrode package opening action." Col. 11, lines 7- 14 (emphasis supplied). An operator using the Nova apparatus, therefore, would look for instructions on the automated external defibrillator display, not on the pouch or package.

None of the cited references discloses or suggests a pouch including an instructive picture that illustrates opening the pouch.

Claim 24, in addition, recites the device of claim 23, wherein the instructive picture includes a symbol representing the handle and wherein the symbol and the handle are of the same color. None of the cited references discloses or suggests any instructive picture that includes any symbol representing any handle. It follows that none of the cited references discloses or suggests any instructive picture in which the symbol representing the handle and the actual handle are of the same color, as recited in claim 24.

Claim 25 recites the device of claim 17, wherein the handle includes directional arrows. As noted above, Walters et al. do not disclose or suggest any handle. First end 14, which the Examiner erroneously equates to a handle, clearly has no directional arrows of any kind, as recited in claim 25. Bishay et al. and Nova et al. likewise include no hint of any handle with directional arrows.

Claim 39, which depends upon claim 35, recites among other elements "an icon printed on the defibrillation electrode that illustrates peeling the defibrillation electrode from the liner." Claim 44, which depends on claim 43, recites a similar element as part of a claimed method. None of the cited references discloses or suggests any icon printed on any defibrillation electrode that illustrates peeling the defibrillation electrode from a liner. For that matter, none of the cited references discloses or suggests any icon printed anywhere that illustrates peeling the defibrillation electrode from a liner.

Claim 54, which depends on claim 53, recites a method that includes "pulling the handle as shown in an instructive picture." None of the cited references discloses or suggests a handle, or an illustrative picture that shows pulling a handle.

For at least these reasons, the rejections of claims 1, 15, 17, 23, 24, 25, 28, 32, 35, 39, 41, 43, 44, 53 and 54 under 35 U.S.C. § 103(a) should be withdrawn.

Rejections in view of Freeman et al.

In the Office Action, the Examiner rejected claims 17, 21 and 22 under 35 U.S.C. § 103(a) as being unpatentable over Freeman et al. (U.S. Pat. No. 5,462,157). Applicants respectfully traverse the rejection.

According to the Examiner, Freeman et al. show all of the features of the invention except a ring-shaped handle. The Examiner concluded, however, that "One of ordinary skill in the art would have found it obvious to modify the tab 40 to have a ring shape because it is well known in the art of packaging materials to use a ring shape so a person opening the package can insert a finger or use the index finger and thumb to grasp the ring shaped tab to assist in opening."

"Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). The Examiner has not made any such showing. There is no evidence in the record that one of ordinary skill in the art would have found it obvious to modify a tab 40 to have a ring shape. The Examiner has proffered nothing more than a conclusory statement, which is not evidence under In re Lee, 61 USPQ2d at 1434-35.

In any event, Freeman et al. fail to disclose or suggest the inventions defined by Applicants' claims 17, 21 and 22, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claim 17 recites a device comprising a pouch containing a defibrillation electrode, the pouch comprising a handle that when pulled causes the pouch to open. Freeman et al. fail to disclose or suggest a handle. Freeman et al. describe two tabs 40 that are pulled away from one another. Freeman et al. col. 3, line 65 to col. 4, line 1. Tabs 40 are not handles, as recited in claim 17, as they represent the flaps of package 10 where a person applies force to open package 10, and force must be applied to both flaps for the package to open.

Claim 22 recites the device of claim 17, wherein the handle is oriented to facilitate pulling in a defined direction. Freeman tabs 40 are not oriented to facilitate pulling in a defined direction. On the contrary, tabs 40 sit side-by-side, and if pulled in any single direction package 10 will not open. According to Freeman et al., tabs 40 must be pulled away from each other in

two different directions, and to do that, the orientations of tabs 40 must be changed with respect to one another.

As the Examiner has admitted, Freeman et al. do not disclose a handle with a ring shape, as recited in claim 21. There is no evidence in the record that one skilled in the art would have been motivated to add two ring-shaped handles (one for each tab, presumably) to a Freeman package. To support a rejection under 35 U.S.C. § 103(a), the Examiner must make particular findings regarding the locus of any such suggestion , teaching or motivation. In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). This the Examiner has not done.

It is true that the Applicants' claimed invention is fairly simple, but the mere fact that Applicants' invention is simple is no basis for denying a patent. In re Oetiker, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992). Applicants submit that Freeman et al., and none of the other cited references, disclose or suggest a pouch containing a defibrillation electrode, the pouch having a handle, ring-shaped or otherwise.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicants' claims 17, 21 and 22 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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By: Daniel J Hanson

SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Daniel J. Hanson
Reg. No.: 46,757